

**SUPPLEMENT TO SEPTEMBER 24, 2004
PROPOSED AMENDMENT TO THE
TENNCARE DEMONSTRATION PROJECT**

**Office of the Governor
State of Tennessee
February 18, 2005**

TABLE OF CONTENTS

	Page
I. Introduction.....	1
II. Reform Components Which Remain Unchanged from the Proposed Amendment	2
A. Eligibility Policies.....	2
B. Out-of-State Services	4
C. Elimination of Coverage for Methadone Clinic Treatment.....	4
D. Three-Tiered Structure for Coverage of Prescription Drugs	5
E. Categorical Exclusion of Two Drug Classes	6
F. Elimination of Coverage of Over-the-Counter Drugs	7
G. 340B Program Initiative.....	8
H. Care Management	9
I. Advisory Commission	10
J. Contractual Arrangements with Managed Care Organizations	11
K. Consolidation to One Behavioral Health Organization	12
L. Information Technology	12
M. Medical Necessity.....	13
N. Fraud and Abuse Initiatives	13
O. Third Party Liability Initiatives	13
III. Proposed Modifications to Certain Reform Components Included in the Proposed Amendment.....	14
A. Transferring Formerly Medically Needy Enrollees to the Demonstration Population	14
B. Cost Sharing.....	15
C. Implementation of Benefit Limits.....	17
1. Pharmacy Benefit Limit.....	17
2. Non-Pharmacy Benefit Limits	18
D. Notice, Appeals and Continuation of Benefits	20
IV. Proposed New Reforms	22
A. Elimination of Pharmacy Coverage for Adult TennCare Standard Enrollees	22
B. Closing Enrollment for the Demonstration Population/Rollovers.....	23
C. Disenrolling Adult TennCare/Medicare Dual Eligibles, Adult Uninsureds and Adult Medically Eligibles	24
D. Enrollment Applications	25
E. Non-Covered Services for TennCare Medicaid and TennCare Standard Populations.....	26
F. Transferring Dual Eligibles to the 1115 Demonstration Project	26

I. Introduction

Tennessee has been working diligently over the last year to develop a plan to restructure our TennCare Demonstration Project (“TennCare”) in a manner that would permit us to maintain coverage while reining in unsustainable growth in program costs. On September 24, 2004, we submitted a proposal to amend our current TennCare program (“Proposed Amendment”). Since submission of the proposal, we have continued to engage in numerous meetings with the public regarding the proposed reform. While many stakeholders have expressed support for this proposed reform, others have asserted multiple legal objections and will likely challenge in court the immediate implementation of some of the reforms contemplated by our Proposed Amendment.¹ Although we have engaged in an extended negotiation process to seek relief under existing Consent Decrees and avoid such challenges, we have been unsuccessful. Because the budget outlook for TennCare is rapidly deteriorating, thereby increasing the amount of savings we will need to achieve in order to stabilize the program, we must now utilize more dramatic reform measures that do not conflict with our existing Consent Decrees in order to satisfy our budget obligations.

We therefore have developed a series of modifications to the Proposed Amendment. While we have seriously considered ending TennCare altogether and returning to a traditional Medicaid program, we want to preserve at least some of the coverage provided through the demonstration. In considering all possible options, our priority is to maintain coverage at current levels for the more than 600,000 children who rely on the TennCare program for care. Accordingly, while we find that we will need to terminate coverage for the adult demonstration population as well as the adult non-pregnant Medically Needy population, we will maintain coverage for children.² In particular, we will preserve Medicaid coverage for children who qualify as Medically Needy and continue TennCare Standard coverage for children in the demonstration population. In addition, while we can no longer afford the unlimited pharmacy benefit that we are currently providing, we propose to limit it and in some cases eliminate it for adults, at this time, we are preserving full pharmacy benefits for children in Medicaid and TennCare Standard.

At the same time, we are aggressively returning to court to seek modifications of the Consent Decrees, where appropriate, that would allow us to adopt the reforms laid out in our September filing, which is our preferred course. Eventually we hope to implement many of these structural reforms that we believe are necessary to place TennCare on a more viable long-term financial path. As this process is likely to stretch out over the next several months, many of the reforms for which we are requesting approval may not be implemented immediately. If we are ultimately able to accomplish these reforms and achieve the necessary level of savings and stability in the

¹ See, e.g., Letter from Gordon Bonnyman, Tennessee Justice Center, to Mark McClellan, Administrator of CMS, dated October 22, 2004.

² For purposes of eligibility, we intend to define TennCare Standard children as enrollees up to age 19. Under current Consent Decrees, we have agreed to provide TennCare Medicaid and TennCare Standard individuals up to age 21 with the same benefit package, e.g., EPSDT services, although we are not required to provide these services to the demonstration population under federal law. Some TennCare Standard enrollees will retain coverage beyond age 19 while the state completes the disenrollment process for these individuals. At this time we do not intend to impose most pharmacy and non-pharmacy benefit limits and exclusions upon such individuals during the disenrollment process.

program, it is our hope that we will be able to restore some of the coverage that we are now proposing to eliminate.

The details of our current proposal are described below. We are seeking approval for (i) reform components that have not changed from the Proposed Amendment, (ii) reform components that were included in the Proposed Amendment but are now being modified and (iii) new components of reform that had not been included in the Proposed Amendment. Despite the changes outlined here, we are retaining coverage for certain vulnerable populations, such as children enrolled in TennCare. Because the basic structure and underlying rationale for the reforms remain unchanged, this proposal is being submitted as a supplement to our September proposal.

We now seek authority to implement the following program changes:

II. Reform Components Which Remain Unchanged from the Proposed Amendment

We are seeking to implement the following reforms that remain unchanged from the Proposed Amendment. For your convenience, below we have included a short summary of each proposed reform, as well as the corresponding request for legal authority (as applicable).

A. Eligibility Policies³

In the Proposed Amendment, the state requested authority to make a variety of eligibility-related changes to the TennCare demonstration program. We have since reformulated some of these requests (as discussed in the following sections of this supplement) but some of the requests remain unchanged. We continue to request authority to make a number of discrete changes to TennCare policies regarding asset tests, coverage for residents of Institutions for Mental Diseases (“IMDs”), limitations on disenrollment from Managed Care Organizations (“MCOs”), coverage for certain newborn children and coverage for certain children in Department of Children’s Services (“DCS”) custody.

Tennessee currently uses asset tests to determine eligibility for most categories of TennCare Medicaid coverage. The state does not, however, presently apply any asset tests to members of the TennCare Standard population as that population is configured today. We are now seeking authority to impose an asset test upon members of the TennCare Standard population. The asset test will not be implemented immediately, and, depending on the composition of the TennCare Standard population in the future, may not be imposed at all. As with our other reforms, we intend to prioritize the needs of children, and therefore would intend to exempt TennCare Standard children from the application of the asset test for as long as possible. The precise application of the asset test would be decided prior to implementation, although in no case would the asset test be more restrictive than is currently applied under TennCare Medicaid for eligibility categories that currently have an asset test. The state therefore renews its request for legal authority to impose appropriate asset tests upon individuals in the TennCare Standard population. In particular, the state requests confirmation of an exception to the following Medicaid requirement for the TennCare Standard population, as well as any other authority

³ See Proposed Amendment, pgs. 23, 25-26, and 60-62 for a more detailed description.

deemed necessary by the Centers for Medicare and Medicaid Services (“CMS”) for the state to implement this reform:

Exception to:

Comparability of Eligibility

Section 1902(a)(17)

To enable the state to utilize different standards for determining eligibility and the extent of medical assistance for TennCare Standard enrollees.

As in our previous submission, Tennessee is also requesting a limited continuation of the IMD waiver that is due to expire on June 30, 2007. Under this more limited waiver, Tennessee would be able to cover care provided to IMD residents *outside* of the institution, but the IMD services themselves would not be covered. Should this limited waiver not be granted, the state plans to implement a “suspension of benefits” policy whereby IMD patients are not disenrolled from TennCare but are only suspended during the time they are in an IMD in order to comply with federal law.

To facilitate this limited continuation of the IMD waiver, the state is requesting the following Costs Not Otherwise Matchable authority, as well as any other authority CMS deems necessary to implement this reform:

Costs Not Otherwise Matchable Authority for:

Expenditures for services to a TennCare enrollee residing in an institution for mental disease that are provided outside of the institution.

Finally, the state still plans to re-establish an annual MCO change period and wishes to clarify that, outside of that period, the state may limit TennCare enrollees’ ability to disenroll from MCOs for good cause. We had previously anticipated re-establishing this annual ballot period in the fall of 2005; we would now anticipate that it will be more feasible to institute this change no later than the fall of 2006. In addition, between the time of CMS approval and the implementation of a new annual ballot period, we will continue to permit TennCare enrollees to disenroll from MCOs for good cause. However, we are seeking the ability to limit the definition of good cause as otherwise required under federal law. (As already authorized under Attachment II.E of TennCare’s Operational Protocol, during this interim period and thereafter, enrollees will be able to request a change in MCOs through the appeals process, as well as by demonstrating medical hardship criteria.) To institute these policy changes, the state therefore requests clarification of the following existing Costs Not Otherwise Matchable authority, as well as any other authority deemed necessary by CMS for the state to implement this reform:

Clarification or Expansion of Existing Costs Not Otherwise Matchable Authority (proposed change to existing authority is in bold):

- *1903(m)(2)(A)(vi), ~~42 C.F.R. 434.27~~, **42 C.F.R. 438.56(d)(2)**, to the extent that the rules in section 1932(a)(4) incorporated therein are inconsistent with the enrollment and disenrollment rules under the demonstration such as restricting an enrollee's right to disenroll within 90 days of enrollment in a new MCO. Enrollees may change MCOs once within the first year of enrollment, and annually thereafter, except that during initial transition enrollment, enrollees may be limited to one change during the first enrollment period which may be less than 12 months but no less than 6 months.*

B. Out-of-State Services⁴

The state is seeking to limit coverage for out-of-state services rendered to both the TennCare Medicaid and the TennCare Standard populations to: (i) emergency services, (ii) services provided by out-of-state in-network providers, or (iii) services provided by out-of-state providers upon the explicit authorization of an MCO or a behavioral health organization (BHO). To implement this reform, the state is seeking the following authority, in addition to any other authority CMS deems necessary to implement this reform:⁵

Waiver of the Following Statutory Provision:

Out-of-State Services

Section 1902(a)(16)

Section 1902(a)(43)

42 C.F.R. 431.52

To permit the state to limit out-of-state services, including EPSDT services, to (i) emergency services, (ii) services provided by out-of-state in-network providers, or (iii) services provided by out-of-state providers upon the explicit authorization of an MCO or BHO.

C. Elimination of Coverage for Methadone Clinic Treatment⁶

Tennessee had requested the elimination of coverage for Methadone clinic treatment for its TennCare population in the Proposed Amendment and we are continuing to request such authority. The unwillingness of Methadone clinics to contract with BHOs in the TennCare Program has created quality of care and public safety concerns, as well as generating an unduly expensive and unwieldy delivery system, requiring direct reimbursement to beneficiaries of costs of Methadone clinic treatment. The state has therefore determined to discontinue its optional coverage of treatment at Methadone clinics for all TennCare enrollees age 21 and older.

⁴ See Proposed Amendment, pgs. 28 and 58 for a more detailed description.

⁵ Please note that though the purpose of our request is identical to our September proposal, we have added further clarification that this limitation upon the definition of out-of-state services will apply to EPSDT services.

⁶ See Proposed Amendment, pg. 29.

We will submit a State Plan Amendment to seek CMS approval of this change in the benefit package available under the state's Medicaid State Plan. The state asks that the demonstration Terms and Conditions, and such other authority as may be necessary or appropriate, be amended to reflect these changes as well.

Although we do not believe any additional waiver of statutory provisions, beyond that already obtained to implement the existing TennCare demonstration project, is required to effect these reforms, we request confirmation of the following authority:

Clarification or Expansion of Existing Waiver:

Amount, Duration and Scope

Section 1902(a)(10)(B)

To permit the state to change the benefits package available to Medicaid eligible adults to exclude coverage or treatment in Methadone clinics, while continuing to cover such services as mandated under federal EPSDT requirements for Medicaid eligible children and as medically necessary for TennCare Standard enrollees under the age of 21.

D. Three-Tiered Structure for Coverage of Prescription Drugs⁷

As the Proposed Amendment submitted to CMS in September explains in greater detail, Tennessee seeks to establish a new, three-tiered structure for the coverage of prescription drugs. Under this structure the state would include a limited number of generic or otherwise relatively low-cost products from most therapeutic drug categories on a preferred drug list.⁸ Coverage of prescriptions for these "A-drugs" would be available without prior authorization. The state's formulary would also include a second category of higher cost "B-drugs," covered prescriptions for any of which would require prior authorization upon confirmation that a clinical scenario exists making its prescription and use appropriate in lieu of a therapeutically comparable "A-drug" on the preferred drug list ("PDL").

All other drugs would be excluded from the state's formulary and would be covered only in very rare, unique and/or novel clinical scenarios pursuant to a very stringent exceptions process. Covered use of any such "C-drug" would require prior authorization based on an individualized showing of medical necessity, as defined by the state. We anticipate that there would be both "A" and "B" drugs available in most drug classes. However, for clinical, health and safety reasons, all products in certain drug classes may be subject to prior authorization (*i.e.*, there may be no "A-drug" in certain therapeutic categories). It is also possible that, for a limited number of drug classes, all products may be categorized as "C-drugs," available as covered services only in cases where the individual and his or her physician can make a sufficient showing of medical necessity.

⁷ See Proposed Amendment, pgs. 35-36 and 59-60 for a more detailed description.

⁸ The cost of a product for these purposes would be determined in a manner that takes into account supplemental rebates that may be offered by the manufacturer on its product.

Pursuant to § 1927(d)(5)(B), an enrollee may be furnished a three-day, interim supply of a prescribed “B” or “C” drug pending disposition of his or her prior authorization request, but only in an emergency situation involving an immediate threat of severe adverse consequences to the enrollee if a covered outpatient drug is not dispensed when a prescription is submitted.

In instituting this reform, the state is sensitive to the potential problems of enrollees transitioning from one drug to another in order to maintain coverage, and will assure that this factor is appropriately taken into account in deliberations respecting the categorization of drugs and prior authorization requests. Moreover, as in all aspects of instituting necessary TennCare reform, the state regards the protection of children as a paramount concern, and will assure that the special health needs of children are appropriately considered in implementing the new three-tiered drug coverage structure.

Clarification or Expansion of Existing Waiver (proposed addition to existing authority in bold):

Pharmacy Benefit Restrictions

Section 1902(a)(54)
Section 1927(d)

To enable the state to establish a formulary and preferred drug list based on cost, therapeutic comparability, and clinical efficacy, and to restrict coverage of drugs for which there are less costly, therapeutically comparable, and clinically efficacious alternatives available by prescription or over the counter, to an extent that would otherwise not be consistent with the provisions of Section 1927(d).

The requested, expanded waiver of Section 1902(a)(54) and 1927(d) would enable the state to impose limitations on drug coverage and institute related prior authorization programs that would otherwise not be consistent with certain provisions of Section 1927(d) of the Social Security Act. We recognize, however, that implementation of an effective prior authorization scheme is currently not permissible under existing Consent Decrees⁹ and therefore we continue to seek relief from those provisions that would otherwise preclude this reform.

E. Categorical Exclusion of Two Drug Classes¹⁰

Tennessee is seeking authority to entirely eliminate coverage of two drug classes for TennCare Medicaid enrollees who are 21 or older.¹¹ Drugs in these classes would not be covered for adults under any circumstances. These drug classes are antihistamines (both sedating and non-sedating forms) as well as products for gastric acid reduction (*i.e.*, H2 blockers and proton pump inhibitors). The state believes that this coverage exclusion is warranted in light of the enormous cost associated with coverage of these two drug classes alone, combined with the fact that

⁹ See Letter from Gordon Bonnyman, Tennessee Justice Center, to Mark McClellan, Administrator of CMS, dated October 22, 2004.

¹⁰ See Proposed Amendment, pgs. 37-38 and 59-60 for a more detailed description.

¹¹ This reform will no longer affect most TennCare Standard enrollees, as the state now proposes to eliminate the drug benefit for those enrollees age 21 and older. See discussion at Section IV.A below.

functionally comparable and appropriately substitutable drugs in these classes are generally available over the counter in non-prescription form.

In order to impose these coverage restrictions, the state seeks the following legal authority, as well as any other authority deemed necessary by CMS for the state to implement the above-described drug class exclusions.¹²

Clarification or Expansion of Existing Waivers of (proposed additions to existing authority in bold):

Amount, Duration and Scope

Section 1902(a)(10)(B)

*To enable the state to modify the Medicaid benefit package to... **(d) cover antihistamines and gastric acid reducers as mandated under federal EPSDT requirements for Medicaid eligible children and as medically necessary for TennCare Standard enrollees under age 21, notwithstanding exclusion of these drugs from the state's formulary for the purposes of treating adult TennCare Medicaid enrollees.***

Pharmacy Benefit Provisions

Section 1902(a)(54)

Section 1927(d)

To enable the state to establish a formulary and implement limitations on drug coverage that would otherwise not be consistent with provisions of Section 1927(d).

We further request that this coverage exclusion be referenced in the Terms and Conditions or such other authority as CMS may deem appropriate. Contemporaneous with submission of this amended demonstration request, we will also submit for CMS approval a State Plan Amendment to categorically exclude coverage of these drug classes for adult beneficiaries.

F. Elimination of Coverage of Over-the-Counter Drugs¹³

Under the present demonstration project, certain OTC drugs may be covered in appropriate situations, when prescribed by a physician. The state seeks to eliminate coverage of all OTC drugs to the extent legally permissible, except for prenatal vitamins (including folic acid supplements) physicians may prescribe for pregnant women, and prescribed OTC drugs as required under federal EPSDT requirements for TennCare Medicaid children or as medically necessary for TennCare Standard enrollees under age 21.

Accordingly, the state is seeking the following legal authority, as well as any other authority deemed necessary by CMS, to impose the above-described coverage restriction:¹⁴

¹² Please note that although we requested this policy change in our September submission, we did not include a separate request for legal authority. Therefore, for clarity here, we have included such a request.

¹³ See Proposed Amendment, pgs. 35-36 and 59 for additional discussion.

¹⁴ Please note that although we requested this policy change in our September submission, we did not include a separate request for legal authority. Therefore, for clarity here, we have included such a request.

Clarification or Expansion of Existing Waiver of (proposed additions to existing authority in bold):

Amount, Duration and Scope

Section 1902(a)(10)(B)

*To enable the state to modify the Medicaid benefit package to... **(e) cover certain OTC drugs for pregnant women (i.e., prenatal vitamins) and cover OTC drugs as mandated under federal EPSDT requirements for Medicaid eligible children, or as medically necessary for TennCare Standard enrollees under age 21, notwithstanding exclusion of OTC drugs from coverage for the treatment of non-pregnant, adult Medicaid eligible TennCare enrollees.***

We further request that this coverage exclusion be referenced in the Terms and Conditions or such other authority as CMS may deem appropriate. Contemporaneous with submission of this amended demonstration request, we will also submit for CMS approval a State Plan Amendment excluding coverage of OTC drugs, with the exception of drugs to which TennCare Medicaid children are entitled under federal EPSDT requirements or as medically necessary for TennCare Standard enrollees under age 21, and certain products for pregnant women.

G. 340B Program Initiative¹⁵

In addition, as previously explained in the September Proposed Amendment, we are seeking statutory waivers requisite to an initiative that would utilize the federal 340B Program as an additional aid in lowering pharmacy costs while maximizing beneficiaries' access to pharmaceutical treatment and promoting appropriate management of care for targeted segments of the TennCare population. This initiative would target such individuals as those with high-maintenance medication needs or certain chronic health conditions, and would involve the state contracting with one or more 340B covered entities for disease or case management services to include pharmaceutical dispensing services. These entities would in turn utilize on-site pharmacies, subcontracts with retail pharmacy networks, or mail-order pharmacy programs to provide pharmaceutical products to beneficiaries at discounted prices and/or to provide covered pharmacy services at significant savings to the state. This initiative would be coordinated and integrated, as appropriate, with the state's other disease management program activities, as described below.

In order to carry out this plan, the state seeks the following authority, as well as any other authority deemed necessary by CMS:

Waiver of the Following Statutory Provision:

Statewideness

Section 1902(a)(1)

To enable the state to contract with one or more health care providers qualified to participate as covered entities in the federal drug discount program established under Section 1927(a)(5) (the 340B Program) for provision of disease management, care

¹⁵ See Proposed Amendment, pg. 38 for additional discussion.

management, telemedicine, or other services to TennCare recipients only in areas of the state where patients can be served by such facilities.

Clarification or Expansion of Existing Waivers of (proposed addition to existing authority in bold):

Amount, Duration and Scope

Section 1902(a)(10)(B)

*To enable the state to modify the Medicaid benefits package...**(f) to permit certain subsets of TennCare enrollees (which may be determined by factors such as geographical location or membership in particular disease populations) to receive pharmacy services or discounts and associated services from a designated provider participating in the federal 340B drug discount program.***

Freedom of Choice

Section 1902(a)(23)

*To enable the state... **(b) to mandate enrollment by recipients within certain target populations in programs for delivery of disease management, case management, telemedicine, or other health care services of providers participating in the 340B program, as well as use by such recipients of the in-house or contract pharmacies of such providers.***

H. Care Management¹⁶

Tennessee is seeking to implement a multi-faceted and innovative disease management program to improve the health outcomes and reduce overall costs of caring for enrollees with certain high cost diseases. This disease management program would be phased-in over time, targeting certain populations (such as SSI adults who are not dually eligible for Medicare and who are not institutionalized) and particular diseases and conditions (such as diabetes mellitus, congestive heart failure, coronary artery disease, asthma, chronic obstructive lung disease, schizophrenia, bipolar disorder and major depression).

At this juncture, the state is seeking the legal authority to implement this care management program, which will provide additional specialized benefits to certain subsets of the TennCare Standard population. In particular, the state requests the following legal authority, as well as any other authority deemed necessary by CMS for the state to implement this reform:

¹⁶ See Proposed Amendment, pgs. 39-41 and 59-60 for a more detailed description.

Clarification or Expansion of Existing Waiver (proposed additions to existing authority in bold):

Amount, Duration, and Scope

Section 1902(a)(10)(B)

*To enable the state to modify the Medicaid benefit package to . . . **(g) provide additional specialized benefits to certain subsets of TennCare enrollees as part of the disease management program.***

Costs Not Otherwise Matchable Authority for:

Expenditures associated with the provision of disease management services to individuals determined to be eligible for TennCare disease management programs.

I. Advisory Commission¹⁷

The state is seeking pre-approval by CMS of a range of modifications, as described in the Proposed Amendment, that the Advisory Commission could recommend based upon the TennCare Bureau's analysis of the TennCare budget. By requesting this upfront authority to implement pre-approved modifications (upon the Advisory Commission's recommendation and the Governor's endorsement or revision of such recommendation), the state gains the ability to implement cost reduction measures when necessary or expand eligibility and/or services when economic conditions permit. We note that depending upon the implementation of certain reforms proposed in this submission (e.g., disenrollment of the uninsured and dual eligible population from TennCare Standard), modifications may need to be made to the range of pre-approved modifications as outlined in the Proposed Amendment. It is our intention that the Advisory Commission and the Governor's implementation of Advisory Commission recommendations will be consistent with the Governor's policy of prioritizing coverage for children.

As some of the modifications that could be adopted through the Advisory Commission process would result in reduced benefits for children in the demonstration population, we are seeking confirmation of a position that CMS has already adopted¹⁸ that EPSDT benefits are not required for children in the demonstration population (i.e., children who are not covered under the state plan). We believe that reconfirmation of such legal authority is encompassed within the following exceptions request, which was included in the Proposed Amendment:

Exception to:

EPSDT

Section 1902(a)(43)

To reaffirm that TennCare Standard enrollees are not entitled to receive federal EPSDT benefits.

¹⁷ See Proposed Amendment, pgs. 41-46 for a more detailed description.

¹⁸ Correspondence from Dennis Smith, Director of CMS, to John Tighe, Deputy to the Governor for Health Policy, July 24, 2002. Correspondence from Charlene Brown for Dennis Smith, Director of CMS, to Gordon Bonnyman, September 24, 2002.

J. Contractual Arrangements with Managed Care Organizations¹⁹

We continue to pursue structural reforms within the MCO system to improve the stability and efficiency of the MCOs and to ensure that high quality care is provided to all TennCare enrollees. For example, Tennessee is requiring all participating MCOs to follow standardized reporting requirements and to adhere to standardized performance measures such as mandatory accreditation by the National Commission for Quality Assurance. We also plan to enhance all financial and quality regulations for our MCOs, as well as bolster our enforcement of these regulations. In the event an MCO fails to achieve these enhanced performance standards, the state would seek to modify or terminate the relationship with this MCO.

We remain concerned, however, that there may not be a sufficient number of MCOs in all regions of the state capable of meeting the standards, therefore resulting in the possible reduction in the number of MCOs statewide. As we anticipate that for certain periods of time Tennessee may have only one MCO operating in certain rural and non-rural areas of the state, we are continuing to request authority to limit MCO choice in order to reach the levels of quality to which we aspire. To facilitate a temporary return to one MCO, the state is requesting the following new authority, as well as any other authority CMS deems necessary to implement this reform:

Clarification or Expansion of Existing Waiver (proposed additions to existing authority in bold):

Freedom of Choice

Section 1902(a)(23)

To enable the state (a) to restrict freedom of choice of provider through the use of mandatory enrollment in managed care plans that would not be consistent with the requirements of 1932 and to permit the state to contract with only one MCO to serve non-rural areas for interim periods of time...

Costs Not Otherwise Matchable Authority for:

Expenditures for services rendered in non-rural areas, including but not limited to the eight urban counties in the Middle Grand Region, even if choice is limited to one MCO in those areas.

The state is seeking to continue the current non-risk administrative services organization (“ASO”) arrangement between the state and the MCOs. We anticipate that in six months time, the MCOs may return to a risk arrangement, if such arrangement is agreed upon by all parties. Finally, the state is also seeking the authority to pay approved, supplemental payments directly to providers outside of MCOs and BHOs under certain situations. Accordingly, the state is requesting the following authority, as well as any other authority CMS deems necessary to implement this reform:

¹⁹ See Proposed Amendment, pgs. 46-48, 60 for a more detailed description.

Costs Not Otherwise Matchable Authority for:

Expenditures for Special Pool Payments made directly to providers.

K. Consolidation to One Behavioral Health Organization²⁰

Tennessee is seeking to have only one BHO operate in each of the three grand regions of the state, possibly resulting in one BHO operating statewide. This request has previously been submitted to CMS, but has not yet been approved. Enrollees' choice would be assured through choice of providers operating within the BHO. Accordingly, the state is seeking a waiver of the following Medicaid requirement, in addition to any other authority deemed necessary by CMS to implement this reform:

Waiver of the Following Statutory Provision:

Methods of Administration

Section 1902(a)(4)(A)

To enable the state to have only one Behavioral Health Organization to provide behavioral health services in a grand region of the state.

L. Information Technology²¹

Tennessee is working towards achieving a centralized clinical information system that will be critical to enhancing the state's ability to manage the TennCare program more effectively and efficiently. In furtherance of this goal, the state is working on the development of a data sharing system in three counties surrounding Memphis, Tennessee over the next five years. Other areas of the state are also forming regional health information organizations, and the state intends to support these important initiatives. To the extent that CMS determines that costs associated with data sharing systems do not meet the standard for routine administrative matching, the state is seeking authority to receive federal match for these costs.

Accordingly, the state is requesting the following authority in addition to any other authority that CMS deems necessary to achieve this goal:

Costs Not Otherwise Matchable Authority for:

Expenditures associated with the implementation of a comprehensive health information technology system, to the extent that they are not matchable as administrative costs under Title XIX.

²⁰ See Proposed Amendment, pgs. 47, 58, and 60 for description of this proposal.

²¹ See Proposed Amendment, pgs. 49-51, 60 for a more detailed description.

M. Medical Necessity²²

A key aspect of the TennCare reform is a newly enacted but not yet implemented statutory definition of “medical necessity.” Consistent with the Governor’s policy to protect children, this definition will be applied as consistent with federal EPSDT requirements. As the definition of medical necessity will be implemented consistent with current federal law and it is within the state’s authority to define what constitutes a medically necessary Medicaid service, the state does not need and is not requesting any waivers or additional legal authority from CMS in relation to this definition. However, we request confirmation from CMS that the state does not need CMS approval prior to the implementation of this medical necessity definition.

N. Fraud and Abuse Initiatives²³

The state has taken a number of different steps to enhance current efforts to combat fraud and abuse within the TennCare program. For example, the state has significantly expanded its capacity within the TennCare Office of Inspector General (“OIG”), separate and distinct from the Medicaid Fraud Control Unit, to significantly enhance the state’s ability to investigate and prosecute recipient fraud. In addition, the state is seeking to disqualify for one year TennCare enrollees who have been convicted under state law of fraud against the TennCare program or the illegal sale of prescription drugs. In the event an enrollee is incarcerated for such a conviction, the state seeks the discretion to apply this disqualification for a period of one year after completion of the sentence. To implement this reform, the state requests the following waiver, in addition to any other authority CMS deems necessary:

Waiver of the Following Statutory Provision:

Comparability of Eligibility

Section 1902(a)(17)

To enable the state to restrict TennCare eligibility in order to disqualify for a period of one year enrollees who have been convicted of a criminal offense involving TennCare fraud or the illegal sale of prescription drugs received from TennCare under state law.

O. Third Party Liability Initiatives²⁴

The state intends to implement various strategies to improve the state’s third party liability (“TPL”) initiatives including but not limited to: (i) expansion of TPL staff, (ii) provision of increased incentives for MCOs and BHOs to engage in cost avoidance of third party recoveries, (iii) expansion of use of contractors for pay-and-chase strategies and (iv) implementation of a small pharmacy-related project to explore TPL options. The state, however, does not need and is not requesting any waivers from CMS to implement this reform, but we believe these reforms will assist Tennessee in reaching its cost-containment goals.

²² See Proposed Amendment, pgs. 51-52 for a more detailed description.

²³ See Proposed Amendment, pgs. 52-53 for a more detailed description and Letter from J.D. Hickey, Deputy Commissioner, Bureau of TennCare, to Joe Millstone, CMS, dated October 12, 2004.

²⁴ See Proposed Amendment, pg. 53 for a more detailed description.

III. Proposed Modifications to Certain Reform Components Included in the Proposed Amendment

A. Transferring Formerly Medically Needy Enrollees to the Demonstration Population²⁵

In the Proposed Amendment, we proposed to reclassify individuals enrolled as non-institutionalized Medically Needy as part of the demonstration population. In this new proposal, we plan to retain Medically Needy pregnant women and children (defined as individuals under 21 years of age) in the Medicaid state plan; these individuals will remain enrolled in TennCare Medicaid. We are now seeking to transfer into the demonstration population all Medically Needy enrollees who are in categories other than Pregnant Women and Children. These enrollees include institutionalized and non-institutionalized persons who are Aged, Blind, and Disabled and people who are caretaker relatives. Some of the individuals in the Aged, Blind, and Disabled categories are dually eligible for Medicare. For those individuals eligible for cost sharing, the state will comply with requirements of Section 1902(a)(10)(E). Accordingly, approximately 97,000 adults enrolled as Medically Needy will be reclassified as demonstration eligibles. We are no longer planning to reclassify women under 65 who need treatment for breast and cervical cancer as TennCare Standard; these optional Medicaid enrollees will retain their current status in TennCare Medicaid and this Medicaid category will remain open to new enrollment.

In conjunction with this Supplement to the Proposed Amendment, we are submitting a State Plan Amendment to close the adult Medically Needy categories (other than Medically Needy pregnant women) effective March 29, 2005 or as soon as possible thereafter. The state will need to coordinate the effective date of this State Plan Amendment with the date of approval of this demonstration program amendment to ensure continuity of coverage. We seek to continue coverage for these individuals as part of the expansion population for the duration of their current eligibility period. Because enrollment into this group will be closed, these individuals will not be able to re-enroll as Medically Needy at the end of their eligibility period. These individuals will be able to apply for enrollment in open Medicaid categories. Any new applicants who apply as adult non-pregnant Medically Needy prior to the closure of the adult non-pregnant Medically Needy categories will be processed and enrolled as Medically Needy if deemed eligible.

In an effort to ensure continuity of care, institutionalized members of the formerly Medically Needy population will retain their current level of coverage (which includes nursing facility services and pharmacy benefits) for the remainder of their eligibility period. Such level of benefits, however, will not be available to any other members of the TennCare Standard population age 21 and older. In the event that TennCare's financial viability improves and the state obtains appropriate relief under the Consent Decrees, we seek to retain the option of reinstating coverage for this population through the Advisory Commission process. The State Plan will still provide coverage for Medically Needy children and pregnant women, and enrollment into this category will remain open.

²⁵ See Proposed Amendment, pgs. 21-25, 58, and 60 for a more detailed description.

In order to transfer some segments of the current Medically Needy population into the demonstration population, we are requesting the following authority as well as any other authority CMS deems necessary for the state to implement this reform:

Costs Not Otherwise Matchable Authority for:

Expenditures for formerly Medically Needy individuals who have been reclassified as part of TennCare Standard and who are no longer covered under the State Plan.

Exception to:

Amount, Duration, and Scope

Section 1902(a)(10)(B)

To permit the state to offer demonstration participants benefits that are not equal in amount, duration and scope to benefits available to other TennCare enrollees and Medicaid recipients and to enable the state to provide a different amount, scope, or duration of benefits or coverage to some segments of the demonstration population than the state provides to other segments.

We also seek to clarify that the Medically Needy adults being moved into the TennCare demonstration population will be treated as “hypotheticals” for the purpose of calculating budget neutrality.²⁶ They will be categorized as Medicaid Eligibility Group 2, defined as “those who could be eligible for Medicaid if Tennessee amended its state plan.” (Medicaid Eligibility Groups, or MEGs, are defined in Attachment B of the current Special Terms and Conditions of the demonstration project.)

B. Cost Sharing²⁷

As explained in the Proposed Amendment, the state is seeking to impose non-nominal co-payments and increase premiums as applicable to the TennCare Standard population. The level of premiums and co-payments will vary according to the enrollee’s income.

We continue to seek authority to implement premium increases as described in the Proposed Amendment. We do not intend, however, to implement these increases in their entirety on an immediate basis and instead seek the flexibility to phase them in at a later date. If the full amount of the increases described in the Proposed Amendment is adopted, we seek the authority to adjust them annually to account for medical inflation. We will continue to require premiums only of TennCare Standard enrollees with incomes at or above poverty. As in the past, we will disenroll TennCare Standard enrollees (after appropriate notice) who have failed to pay the premiums.

In a change from the Proposed Amendment, we will no longer be able to eliminate the current cost sharing requirements, including those for pharmacy, for children in TennCare Standard who

²⁶ The treatment of the costs associated with Medically Needy dual eligibles will be treated consistently with the costs of other dual eligibles, discussed at pg. 24 below.

²⁷ See Proposed Amendment, pgs. 29-31, 62 for a more detailed description.

have incomes at or above poverty. Instead, the state intends to continue to impose cost sharing obligations upon children in TennCare Standard at a level that would not exceed currently authorized levels. We also seek authority to impose higher copayments (up to the levels identified in the Proposed Amendment) on adult members of TennCare Standard, although depending on the timing of the disenrollment of the adult demonstration population envisioned in this Supplement, the state may not need to implement this change. At a later date the state may decide to impose the higher copayments identified in the Proposed Amendment for children; though at this time it is not our intent to do so.

The state already has authority in its Operational Protocol to deny services for failure to make pharmacy co-payments by TennCare Standard enrollees. As proposed in September, we are also seeking authority to deny other services for failure to make co-payments by TennCare Standard enrollees. At this time, however, we do not intend to deny services for children in TennCare Standard who fail to make co-payments; though we may do so at a later date. Finally, as originally described in September, we are proposing to remove the current Out-of-Pocket (“OOP”) maximums presently applied to the TennCare Standard population, including children.

Formerly Medically Needy adults moving to TennCare Standard (who are not currently subject to cost sharing) will not be subject to TennCare premium and co-payment requirements while they remain enrolled in TennCare Standard.

To confirm that the state continues to have the authority to increase premium obligations and impose non-nominal co-payments upon the TennCare Standard population, we request the following:

Exception to:

Premiums and Cost Sharing

Section 1902(a)(14)
Section 1916
42 C.F.R. 447.53

To permit the imposition of premiums in excess of standards otherwise prescribed by the Secretary and cost sharing that is more than nominal upon TennCare Standard enrollees, and to permit denial of services for TennCare Standard enrollees who fail to pay co-payments and disenrollment for TennCare Standard enrollees who fail to pay premiums.

In addition, while pharmacy co-payments for TennCare Standard enrollees outlined in the September Proposed Amendment are no longer at issue in light of more recently recognized necessity to eliminate pharmacy benefits for this demonstration population, the state now proposes to institute a nominal level of cost-sharing by most Medicaid eligible adults age 21 and older in their pharmaceutical treatment. We propose to ask Medicaid eligible adults with the exception of those receiving services described in Section 1916(a) and (b) of the Social Security Act and federal regulations at 42 C.F.R. § 447.539(b) (*i.e.* services to pregnant women, services to institutionalized individuals, family planning services and supplies furnished to individuals of child-bearing age, emergency services as described in § 447.53(b)(4), and services to individuals receiving hospice care) to make nominal co-payments towards their pharmaceutical expenses, on

a graduated scale depending upon whether the prescription drug dispensed is a generic, branded, or non-formulary drug. It should be noted that the exception from cost-sharing requirements for emergency services generally will not apply in circumstances where a pharmacy dispenses an interim supply of a prescribed drug to an enrollee, pending disposition of a prior authorization request.

We believe we currently have the authority to establish the above-described pharmacy co-payment schedule for adult TennCare enrollees as described above. To the extent we do not possess such authority, we request any other authority CMS deems necessary to implement this reform.

With submission of this amended demonstration request, we will also submit for CMS approval a State Plan Amendment to establish nominal co-payments for prescription drugs dispensed to adult TennCare Medicaid enrollees.

C. Implementation of Benefit Limits

As described further below, Tennessee is intending to exempt children under 21 enrolled in TennCare from pharmacy and non-pharmacy benefit limits. We generally intend to define TennCare Medicaid children as enrollees up to age 21 and TennCare Standard children as enrollees up to age 19.²⁸ TennCare Medicaid children will not be subject to these limits when services are mandated under federal EPSDT requirements. TennCare Standard enrollees under age 21 will also be exempt from these benefit limits as under current Consent Decrees, at this time the state has agreed to provide TennCare Medicaid and TennCare Standard individuals up to age 21 with an equivalent package of benefits, e.g., EPSDT services. Because we are not required to provide these services to the TennCare Standard population of persons under 21 under federal law, we reserve the right to change such policy at a future date.

1. Pharmacy Benefit Limit²⁹

In addition to the other pharmacy coverage reforms potentially affecting TennCare Medicaid enrollees outlined in the Proposed Amendment, the state seeks authority to impose a limit on pharmacy coverage for all adults eligible to receive medical assistance under Title XIX of the Social Security Act (adults in the TennCare Medicaid population) of four prescriptions per month. These monthly benefit limits will not apply to TennCare Medicaid children who are eligible under Title XIX to receive pharmacy benefits as mandated by EPSDT or to TennCare Standard enrollees under age 21, as medically necessary. The state intends to expand this exemption from pharmacy benefit limits to TennCare Medicaid enrollees who receive services in nursing facilities, intermediate care facilities for the mentally retarded (“ICF/MRs”), or who receive services under a Home and Community Based Services (“HCBS”) waiver.³⁰ The

²⁸ As noted previously, some TennCare Standard enrollees will retain coverage beyond age 19 while the state completes the disenrollment process for these individuals. At this time we do not intend to impose most pharmacy and non-pharmacy benefit limits upon such individuals during the disenrollment process.

²⁹ See Proposed Amendment at pg. 27 for a more detailed description.

³⁰ In anticipation of expanding the exemption to adult NF, ICF/MR and HCBS populations, the state is requesting waiver authority sufficient for this expansion. However, the state seeks confirmation that an exception of these populations from the otherwise applicable monthly benefit limit would comport with federal standards under the

maintenance of the expansion to the exemption may be contingent upon the state's obtaining appropriate legal and financial relief.

While we anticipate that the four prescription limit will apply to the vast majority of drug classes, there will be exceptions from application of this limit, as will be specified by the state in its Title XIX State Plan. For example, excluded drugs are expected to include drugs for renal patients (such as iron preparations and dialysis medications), TPN (Total Parenteral Nutrition), antineoplastic agents, clotting factors, antiviral agents specific to treatment of HIV/AIDS, agents for treatment of Hepatitis C and tuberculosis, flu vaccine for individuals in high risk categories, and prenatal vitamins. To the extent the scope of the exemptions may be expanded or modified in the future, the state will submit a further State Plan Amendment as appropriate. (To the extent that pharmacy services might fall under the definition of emergency services, this four prescription limit will similarly apply as further explained in Section III.C.2 below.)

With submission of this supplement to the Proposed Amendment, we are submitting for approval a State Plan Amendment that would reflect and implement the four prescription limit for adult Title XIX beneficiaries as described herein. We also request that the new prescription benefit limit for the adult Medicaid population be referenced in the Terms and Conditions or other documentary authority, as appropriate.

In addition to submitting a State Plan Amendment in conjunction with this proposal, we are seeking the following legal authority in order to establish the four-prescription limit as described above, as well as any other authority CMS may deem necessary for the state to implement this reform:

Clarification or Expansion of Existing Waiver of (proposed additions to existing authority in bold):

Amount, Duration and Scope

Section 1902(a)(10)(B)

*To enable the state to modify the Medicaid benefit package to...**(h) provide coverage of prescription drugs for eligible Medicaid and TennCare Standard children, and for individuals receiving benefits in nursing facilities, intermediate care facilities for the mentally retarded or who receive services under a home and community based services waiver, that exceeds the four prescription per month limit generally applicable to adult beneficiaries in the TennCare Medicaid population.***

2. Non-Pharmacy Benefit Limits³¹

In the Proposed Amendment, we sought to impose certain benefit limits upon individuals within the TennCare Standard population, with exemptions for certain vulnerable populations (i.e.,

Americans with Disabilities Act ("ADA"), as presently construed by the responsible agencies. If the exception of adult NF and ICF/MR residents from the pharmacy benefit limit were to be deemed inconsistent with ADA requirements, the state would apply the four prescription limit to all adult Medicaid enrollees, irrespective of residence in any institutional facility

³¹ See Proposed Amendment, pgs. 26-29 and 61 for a more detailed description.

children under age 21, pregnant women and persons with disabilities). Though we continue to seek authority to impose limits on some benefits, we seek to implement these limits differently than originally proposed. Specifically, we propose to apply benefit limits to adults age 21 and older in both the TennCare Medicaid and TennCare Standard population (contingent upon the existence of an adult TennCare Standard population); the only exemption from non-pharmacy benefit limits will now be for children under age 21 in both populations. (We may also determine at a later date that adult TennCare Medicaid and/or TennCare Standard enrollees in nursing facilities, ICF/MRs or who receive services under a HCBS waiver should be exempt from these benefit limits. The decision to exempt these populations will be dependent upon the state's ability to obtain appropriate legal and financial relief through other aspects of proposed reforms.) We also propose a modified benefit limit structure and, in particular, seek to modify the number of inpatient and outpatient day limits.

We request that such non-pharmacy benefit limits be referenced in the Terms and Conditions or other authority as may be appropriate. In addition, prior to implementation we will submit amendments to our State Medicaid Plan to reflect these limits for the adult TennCare Medicaid population. The non-pharmacy benefit limits we propose are as follows:

- Inpatient hospitalizations — 20 days per enrollee per year for TennCare Medicaid; 5 days per enrollee per year for TennCare Standard;
- Physician outpatient services — 12 visits per enrollee per year for TennCare Medicaid and TennCare Standard;
- Outpatient facility services — 8 visits per enrollee per year for TennCare Medicaid, 3 visits per enrollee per year for TennCare Standard;
- Lab and X-ray — 10 occasions per enrollee per year for TennCare Medicaid and TennCare Standard.

In a departure from our September proposal, behavioral health services may be included in the application of these non-pharmacy benefit limits. We do, however, continue to seek authority to identify a short-list of encounter types and products that will continue to be available, despite the application of these non-pharmacy benefit limits. In addition, we plan to implement the state's existing authority to limit inpatient and outpatient substance abuse services to \$30,000 in lifetime benefits for all adult TennCare enrollees age 21 and older, regardless of whether or not the adult is also considered to be Severely and/or Persistently Mentally Ill ("SPMI"), as described in the Proposed Amendment.

We believe the existing waiver of "amount, duration, and scope" requirements contained in Section 1902(a)(10)(B) is sufficient authority to enable us to implement these changes for the TennCare Medicaid and Standard populations. To the extent CMS believes any additional authority is necessary, we hereby request such authority as well.

As in the Proposed Amendment, we anticipate that both pharmacy and non-pharmacy benefit limits will apply to any emergency and non-emergency services provided to TennCare enrollees. (Though as we proposed in September, screenings required under the Emergency Medical Treatment and Labor Act will be exempt from these non-pharmacy benefit limits.) Accordingly, to implement this proposal, we are seeking approval for costs not otherwise matchable in a

manner that would allow the state, MCOs and BHOs to deny coverage of certain services when these services exceed non-pharmacy benefit limits. In particular, we request the following authority, and any other authority that CMS may deem necessary:

Costs Not Otherwise Matchable Authority for:

Expenditures under contracts that do not meet the requirements of Section 1903(m) of the Act specified below:

- *1903(m)(2)(A)(xii), 42 C.F.R. 438.114 to the extent that requirements of Section 1932(b)(2) are inconsistent with any applicable non-pharmacy benefit limits that may result in the denial of coverage for emergency services or post-stabilization services by the state, MCOs or BHOs.*
- *1903(m)(2)(A)(xii), 42 C.F.R. 438.206(b)(3) to the extent requirements of Section 1932(c)(1)(A)(i) are inconsistent with any applicable non-pharmacy benefit limits for the TennCare population that may result in the denial of coverage for second opinions.*

D. Notice, Appeals and Continuation of Benefits³²

As proposed in September, the state is seeking some flexibility and clarification with respect to notice, appeals and continuation of benefit rights for the imposition of benefit limits and co-payments for the TennCare Standard population. This flexibility is necessary in order to be able to implement and enforce the benefit limit and co-payment policies effectively. Because we are proposing to apply these policies to the TennCare Medicaid as well as TennCare Standard population, however, we must now also seek the associated notice, appeals and continuation of benefits flexibility for our Medicaid enrollees in the imposition of benefit limits. Similar flexibility relating to appeals by Medicaid beneficiaries will also be necessary in order for the state to effectively implement the three-tiered structure for coverage of prescription drugs outlined in Section I.D of this proposal. We acknowledge, however, that modification of the Consent Decrees will be necessary before any of these changes can be implemented. We are not requesting any waivers from CMS in relation to the ability of enrollees to seek an appeal of determinations of the medical necessity of covered services.

Recognizing that enrollees are entitled to due process protections, the state intends to develop notice and appeals procedures that comply with Constitutional standards, while still affording the state with the flexibility it requires to implement these proposals effectively. However, the requisite procedures may vary depending on the service involved, and the state believes that its role in defining this process may appropriately be expanded where the Medicaid statute does not entitle the beneficiary to receipt of the type of services at issue.

³² See Proposed Amendment, pgs. 31-33, 62 for a more detailed description.

The state, MCOs³³ and providers will provide TennCare enrollees with notification informing enrollees of their appeal rights. For example, (i) Tennessee and/or MCOs will provide advance written notice of TennCare's imposition of benefit limits, co-payments and premiums generally, (ii) Tennessee and/or MCOs will provide written notice to enrollees upon denial of payment to providers for services rendered to enrollees who have exceeded a benefit limit or denial of payment to providers due to lack of required prior authorization for services, and (iii) providers or suppliers will provide oral and/or written notice upon or after denial of services for failure to make a co-payment (only applicable to TennCare Standard enrollees), because the enrollees have exceeded a benefit limit or because of lack of required prior authorization for services. The state will permit appeals by TennCare enrollees of factual disputes relating to benefit limits, co-payments and prior authorization disputes to proceed to a hearing if not otherwise resolved, but will retain the authority to determine whether an appeal is based on factual disputes. Continuation of benefits that are the subject of the factual dispute will not be permitted during the pendency of allowable factual appeals. But Tennessee will provide retroactive coverage in the event of successful factual appeals.

With respect to pharmacy coverage determinations, the state anticipates drawing a distinction between appeal rights of, on the one hand, beneficiaries who are denied coverage of "B" or "C" drugs for which no prior authorization has been sought, and on the other hand, beneficiaries on whose behalf requests for prior authorization for prescription of non-preferred or non-covered drugs have been made but denied, based upon the state's application of clinical criteria. Enrollees will be able to appeal from denials of requests for prior authorization of coverage for B or C drugs, and will have a full opportunity in such appeals to challenge the factual predicates for any denial of a prior authorization request. No coverage of B or C drugs, however, will be available in the absence of prior authorization that has been properly obtained under the procedures established by the State. Where an enrollee or his/her provider refuses or fails to follow these procedures, coverage of the drug will not be authorized, and there will be no prior authorization determination or denial from which an appeal can be taken.

In the Proposed Amendment, we requested legal authority in the form of an exception to Medicaid fair hearing requirements for the TennCare Standard population. Since we are now proposing to include TennCare Medicaid enrollees in our new benefit limit policies and are anticipating appeals by TennCare Medicaid enrollees of such limits and of drug coverage determinations relating to the proposed new preferred drug list ("PDL") and formulary structure, we are seeking authority in the form of a waiver to utilize such notice, appeal and continuation of benefits processes. The requested authority specified below is in addition to as any other authority CMS deems necessary for the state to implement this process.

Waiver of the Following Statutory and Regulatory Provisions:

Fair Hearings

*Section 1902(a)(3)
42 C.F.R. 431, Subpart E*

³³ In the event that the state makes the decision to include behavioral health services in the future benefit limits, BHOs will also be required to provide notification to enrollees with respect to these services.

To provide the state with the authority to implement an appropriate notice, appeals and continuation of benefits process for TennCare enrollees who would seek to challenge the implementation of benefit limits, co-payments, and prior authorization requirements.

Costs Not Otherwise Matchable Authority for:

Expenditures under contracts that do not meet the requirements of Section 1903(m) of the Act specified below:

- *1903(m)(2)(A)(xii), 1932(b)(4), 42 C.F.R. 438, Subpart F to the extent that these requirements would preclude the state and MCOs from implementing an appropriate notice, appeals and continuation of benefits process for TennCare enrollees who would seek to challenge the implementation of benefit limits, co-payments and prior authorization requirements.*

IV. Proposed New Reforms

A. Elimination of Pharmacy Coverage for Adult TennCare Standard Enrollees

In the Proposed Amendment, the state proposed to impose a six prescription per month limit on pharmacy coverage³⁴ for TennCare Standard enrollees in non-exempt categories.³⁵ However, due to a variety of factors, including threatened legal challenges arising from existing Consent Decrees, it has become apparent that more stringent limitations on drug coverage will need to be imposed in order to control rising programmatic costs for pharmacy while still attempting to provide TennCare enrollees as wide access as possible to needed drug therapies. To that end, the state is withdrawing its request for approval of a six-prescription limit on TennCare Standard enrollees, but instead seeks to eliminate the pharmacy benefit for TennCare Standard enrollees age 21 and older. The state is hopeful that at some later date it may be financially feasible to except certain other segments of the TennCare Standard population from this benefit limitation.

We request approval of this amendment to the demonstration project, including revision of any previous waivers or authority for federal funding of costs not otherwise matchable that previously enabled the state to provide pharmacy benefits to the adult TennCare demonstration population, and request that this reduction of the TennCare Standard benefits package be referenced in the Terms and Conditions or other documentation or authority, as appropriate.

Although we do not believe any new or expanded waiver of statutory compliance or any amendment of the state's Title XIX State Plan is needed to implement this reform, we nevertheless request confirmation of the following exception:

³⁴ See Proposed Amendment at pg. 27.

³⁵ Children, pregnant women, and disabled individuals were intended to be exempt from this limitation. See Proposed Amendment at pg. 26.

Exception to:

Pharmacy Benefit Restrictions

Section 1902(a)(54)

Section 1905(a)(12)

Section 1927(d)

To clarify that the state may eliminate coverage of outpatient drugs from the benefits package provided to demonstration populations.

B. Closing Enrollment for the Demonstration Population/ Adult Rollovers

We are seeking the authority to close new enrollment for the entire demonstration population. Pursuant to TennCare's Operational Protocol, we currently possess the authority to close enrollment for the demonstration population (or TennCare Standard), with the exception of those individuals who are found to be Medically Eligible with incomes below 100% of poverty. Therefore, we have maintained continuous open enrollment for this subset of the expansion population from 2002 to the present, although enrollment for all other TennCare Standard categories is currently closed (pursuant to our authority to only open enrollment upon action by the General Assembly when there is available federal and state funding).

In accordance with TennCare's Operational Protocol, when enrollees lose their eligibility for TennCare Medicaid, we also possess the authority to enroll individuals who are eligible for TennCare Standard without a break in coverage (unless the individual is incarcerated or has moved permanently out-of-state). After these individuals "rollover" into TennCare Standard, they have their eligibility for TennCare Standard re-established on at least an annual basis.

In an effort to contain costs and protect the coverage available to existing enrollees, Tennessee seeks now to close enrollment, effective upon CMS approval, for those Medically Eligibles with incomes below 100% of poverty as well as adults age 19 and over who lose their eligibility for TennCare Medicaid and rollover into TennCare Standard. (We are also seeking the authority to terminate adult Medically Eligibles as well as adults in other demonstration categories, defined as persons age 19 and older. See Section IV.C.) Because TennCare Standard will now include formerly Medically Needy adults (excluding pregnant women), we seek authority to close enrollment for this population as well. However, the state will process applications from individuals for open eligibility categories prior to CMS approval of this demonstration amendment. Eligible individuals will be enrolled until their eligibility category is terminated, as discussed below. We also clarify that children (under age 19) losing eligibility for TennCare Medicaid will continue to be able to rollover into TennCare Standard if they meet eligibility requirements and follow appropriate application and enrollment procedures.

Because the Medically Needy are only enrolled until they are reprocessed after approximately one year of eligibility, the enrollment closure will mean that coverage of formerly Medically Needy adults in TennCare Standard will terminate at the end of their current eligibility period.

The state therefore requests the authority to close enrollment for the entire demonstration population, pursuant to the following proposed addition to TennCare's current Terms and Conditions, as well as any other authority CMS deems appropriate:

Addition to Special Terms and Conditions:

At its sole discretion the state possesses the authority to close enrollment in TennCare Standard at any time for all individuals who are not eligible for Medicaid, including but not limited to individuals who qualify as Medically Eligible with incomes that are below 100% poverty.

C. Disenrolling Adult TennCare/Medicare Dual Eligibles, Adult Uninsureds and Adult Medically Eligibles

In an effort to achieve a more viable financial future for the TennCare Program, we request authority to terminate coverage for adult TennCare Standard enrollees. (We seek to define TennCare Standard adults as individuals who are at least 19 years old.) Specifically, we request authority to terminate coverage upon CMS approval for the 38,000 so-called "grandfathered" TennCare/Medicare dual eligibles who were eligible for TennCare Standard and Medicare (but not TennCare Medicaid) as of December 31, 2001, and who have remained continuously eligible in this category since that time. These persons will retain coverage under Medicare after their disenrollment from TennCare. In addition, we propose terminating coverage, upon CMS approval, for approximately 121,000 members of the uninsured population in TennCare Standard who are 19 years of age or older. We are also proposing terminating coverage for approximately 67,000 members of the Medically Eligible population who are 19 years of age or older, which may occur at a later date.

Tennessee proposes to clearly define eligibility of children in the TennCare Standard population as individuals up to age 19. We will retain coverage for existing dual eligible, uninsured and Medically Eligible children until they "age out" of the program at age 19, although, as noted above, new enrollment for these categories will be closed. Consistent with current policy, uninsured children will be disenrolled prior to reaching age 19 if they no longer meet the criteria for TennCare Standard.

We also clarify that as the state is seeking the authority to terminate the various categories of eligibility for adult TennCare Standard, upon CMS approval, adult TennCare Standard enrollees will no longer be able to "switch" from one TennCare Standard category to another. Instead, adults over age 19 will retain their status in the category for which they are currently eligible at the time of CMS approval. Children in TennCare Standard (under age 19), however, will retain the ability to switch from different categories of eligibility in TennCare Standard (i.e., from uninsured to Medically Eligible if their family income exceeds the limit for uninsured and they meet the criteria for Medically Eligible).

Though we regret taking these steps, at this juncture, we are left with few options for continuing coverage for parts of the demonstration population. In the event that our financial and legal

situation improves, we will have the option of reinstating coverage through the Advisory Commission process.

We therefore request authority to terminate this coverage pursuant to the proposed addition to TennCare's current Terms and Conditions, as well as any other authority CMS deems appropriate:

Additions to Special Terms and Conditions:

At its sole discretion, the state possesses the authority to disenroll "grandfathered" TennCare/Medicare dual eligibles who were eligible for TennCare Standard and Medicare (but not TennCare Medicaid) as of December 31, 2001 and who have remained continuously eligible in this category since that time. These individuals will retain coverage under Medicare after their disenrollment from TennCare.

At its sole discretion, the state possesses the authority to disenroll adult uninsureds (defined as persons age 19 and older) currently eligible for TennCare Standard.

At its sole discretion, the state possesses the authority to disenroll adult Medically Eligibles (defined as persons age 19 and older) currently eligible for TennCare Standard.

We also seek to clarify that in disenrolling uninsured, dual eligible and Medically Eligible members of the TennCare Standard population, the state is not required to perform an ex parte redetermination for these individuals. We are similarly seeking to confirm that the state is not required to perform an ex parte redetermination for those formerly Medically Needy members of the TennCare Standard population when their coverage lapses at the end of their current eligibility period. To clarify this authority, we request a confirmation of an exception to the following Medicaid requirements, in addition to any other authority CMS deems appropriate:

Exception to:

Continuous Enrollment

*Section 1902(a)(4)
Section 1902(a)(8)
42 C.F.R. 435.916(c)
42 C.F.R. 435.930*

To permit the state to reclassify and disenroll TennCare Standard enrollees without performing an ex parte redetermination for those enrollees, provided that such enrollees are permitted to reapply under open Medicaid eligibility categories.

D. Enrollment Applications

In the current demonstration project, there is a provision for preserving an "effective date of application" for Medicaid eligibles if individuals and/or their representatives need to apply for Medicaid at a time when Department of Human Services ("DHS") offices are closed (such as state holidays or weekends). In these situations, the individual and/or his/her representative may

fax an application to the DHS office. The effective date of the application, if approved, is the day the application was faxed. The state wishes to retain the flexibility to move away from this policy in the future and to require a follow-up application to be filed with DHS. The effective date would then be the day that the application is actually filed at DHS.

E. Non-Covered Services for TennCare Medicaid and TennCare Standard Populations

The state is proposing to non-cover dental services and private duty nursing services for TennCare enrollees age 21 and older. Tennessee has previously received authority to non-cover private duty nursing services for adults but now seeks to implement that authority. Therefore, we request that the non-coverage of dental and private duty nursing services for TennCare enrollees age 21 and older be referenced in the Terms and Conditions or other authority as CMS may deem appropriate. In addition, where applicable, we are simultaneously submitting revisions to our State Medicaid Plan to reflect these exclusions for the TennCare Medicaid population. To implement these reforms, we also request confirmation of exception to the following Medicaid requirement, as well as any other authority CMS deems necessary to implement this reform:

Exception to:

Amount, Duration and Scope

Section 1902(a)(10)(B)

To permit the state to offer demonstration participants benefits that are not equal in amount, duration and scope to benefits available to other TennCare enrollees and Medicaid recipients and to enable the state to provide a different amount, scope, or duration of benefits or coverage to some segments of the demonstration population than the state provides to other segments.

F. Transferring Dual Eligibles to the 1115 Demonstration Project

Currently, individuals who are dually eligible for TennCare and Medicaid receive services (other than Medicare cost-sharing) through TennCare MCOs pursuant to our 1915(b) demonstration program. We propose to transfer these individuals to the 1115(a) demonstration program. All dual eligibles except for those in the adult non-pregnant Medically Needy categories will be transferred to TennCare Medicaid. Medically Needy dual eligibles will be transferred to TennCare Standard. Once the transfer is approved, we will terminate the 1915(b) demonstration as it would no longer be necessary. The costs for these individuals would be “passed through” the TennCare demonstration program; that is they would not count towards the budget neutrality calculation. This transfer will be transparent to the individuals affected.